Docket No: **20481/0206417-US0**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Per Holm and Tomas Norling

Serial No.: 10/513,807 Art Unit: 1615

Confirmation No.: 7864

Filed: November 8, 2004 Examiner: Melissa S Mercier

For: SOLID DOSAGE FORM COMPRISING A FIBRATE

DECLARATION OF TORBEN ELHAUGE PURSUANT TO 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Torben Elhauge, declare as follows:

1. I am a citizen of Denmark and over 21 years of age. I have been a Research Scientist at LifeCycle Pharma A/S, the assignee of the above-identified application, since February 1, 2005. I have over 13 years of experience in the field of analytical development and control of pharmaceutical formulations including 6 years of experience as Research Scientist at the Danish Medicines Agency, 2 years of experience as Validation Chemist at Statens Serum Institut (SSI, Denmark) and 4 years of experience as Analytical Chemist at the pharmaceutical

company Nycomed DAK. I have a B.Sc. (1990) and M.Sc. (chemical engineering/analytical chemistry, 1992) from the Technical University of Denmark.

2. I have reviewed the application as filed on November 8, 2004, the pending claims, the claims as amended in the accompanying Amendment, and the Office Action mailed November 2, 2006.

3. Fenofibrate tablets of the present invention were prepared as follows: Solid PEG 6000 was placed in a vessel and liquefied (melted) by heating. Fenofibrate (conventional crystalline API) was added and the mixture was stirred and heated until all fenofibrate was dissolved while the maximum temperature of the mixture was maintained at or below 78 degrees Celsius. Poloxamer 188 was added to the mixture under stirring and heating. The liquid mixture was sprayed onto lactose monohydrate carrier particles in fluid-bed equipment. The resulting granulate was sifted and blended with magnesium stearate (lubricant) and the blend was directly compressed into tablets. The tablets contain 18.9 %w/w of fenofibrate; 24.9 %w/w of PEG 6000; 10.5 %w/w of Poloxamer 188; 44.4 %w/w of lactose monohydrate; and 1.3 %w/w of magnesium stearate. The tablets were stored at 5 degrees Celsius until analyzed.

4. In order to determine the microstructure of the fenofibrate tablets, confocal Raman microscopy (CRM) was performed on cross sections of the fenofibrate tablets.

5. For each tablet, Raman spectra and maps were generated for both a 100 μm^2 outer section and 100 μm^2 inner section of the respective tablet. Spectra were acquired using a Witec Confocal Raman Microscope equipped with a 532 nm laser source. The excitation source was focused using an objective and the scattered light was collected using an 180° backscatter regime (collected using the same objective), with the laser line intensity being suppressed through the

use of an edge filter. The Stokes shifted Raman scatter was dispersed using a 600 grooves/mm grating onto a Charged Coupled Device (CCD).

6. The Raman maps were constructed through the use of a serial mapping process, which involves the acquisition of spectra at defined points within an array, using a CCD. Reference spectra of the fenofibrate, lactose, poloxamer 188 and PEG 6000 were fitted to the acquired array of spectra to produce Raman maps.

7. The results from these experiments indicate that fenofibrate is present in crystalline form, for all three tablets tested. Exhibit B is a representative result for a fenofibrate tablet. The Raman peak generated for fenofibrate from the outer section of the tablet (bottom), a crystalline fenofibrate reference (middle) and an amorphous fenofibrate reference (top) are all shown. The fenofibrate in the tablet is consistent with the crystalline fenofibrate reference, as the Raman peaks are sharp and jagged for both.

8. It is therefore my opinion that the fenofibrate formulations described and exemplified in the instant application contain crystalline fenofibrate - not fenofibrate in a dissolved state.

9. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the instant application or any patent issued thereupon.

01 MAY 07
DATED

TORBEN ELHAUGE

EXHIBIT B

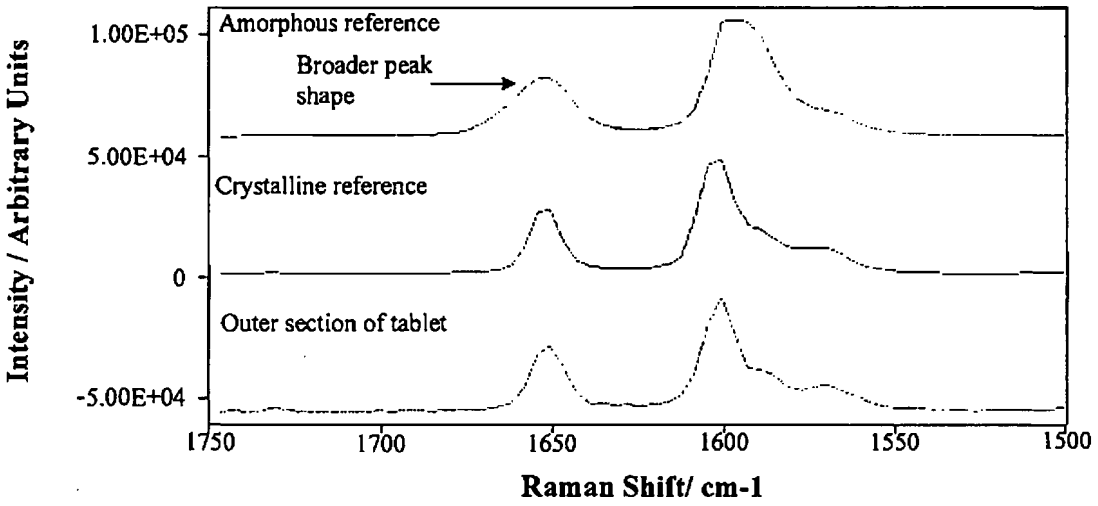

Exhibit B. Raman spectra of the fenofibrate amorphous reference (top), fenofibrate crystalline reference (middle), and a point from the outer section of a tablet of the present invention (bottom).